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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/780,929

02/08/2001

Ronald Breaker

MBHB00,884-H (500/001)

6724

20306

7590

07/01/2002

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EXAMINER

SCHULTZ, JAMES

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/780,929

Applicant(s)

BREAKER ET AL.

Examiner

James Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-40, and 46-48 are drawn to nucleic acid ribozymes, and vectors encoding said ribozymes, and cells transformed with said vectors, classified in class 435, subclass 24.5.
- II. Claim 41 is drawn to a method of modulating gene expression in a plant cell by administering a nucleic acid, classified in class 800, subclass 278.
- III. Claim 42 is drawn to a method of modulating gene expression in a mammalian cell by administering a nucleic acid, classified in class 435, subclass 375.
- ~~III~~  
IV. Claims 43-45 are drawn to methods of cleaving a nucleic acid molecule by contacting it with the ribozyme molecule of claim 1 or 2, classified in class 435, subclass 6.

Invention I is related to inventions II-IV as a product and processes of its use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of group I is used both in the methods of groups II-III, which claim to modulate gene expression, and also in group IV to cleave a target gene transcript, resulting in the modulation of gene transcription. There are several types of compounds that exist in addition to the ribozymes of the instant invention that are capable of said gene modulation or transcript cleavage; antisense RNA sequences, iRNA,

Art Unit: 1635

triple helix formation, and DNazymes are all capable of these actions. Therefore, the process for using the product as claimed can be practiced with another materially different product, and thus comprise different inventions.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is proper because these methods appear to constitute patentably distinct inventions for the following reasons. Groups II and III are directed to methods of modulating gene expression in mammalian and plant cells, which are fundamentally different cell types. Transformation of plant cells require passing nucleic acids through the plant cell wall which presents a significant barrier that is absent in mammalian cells, thus the steps required in said methods would be materially different. Groups II and III are directed to gene modulation exclusively in cells, whereas the method of group IV is directed gene transcript cleavage, which embraces a cell free system. Thus the steps involved require materially different steps, and a search and examination of all three methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, the classification is different, and the subject matter and steps are divergent.

Applicant is directed to select one of the <sup>four</sup>~~three~~ claim groups outlined above for prosecution on its merits.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James D. Schultz, PhD  
June 19, 2002



ANDREW WANG  
PRIMARY EXAMINER